

**Citation:**

*Hypertens Res.* 2006;6:389-396.

**PubMed ID:** [16940700](#)

**Study Design:**

Randomized Controlled Trial

**Class:**

A - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**



NEUTRAL: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

The purpose of the research was to determine if increasing consumption of yellow-green Okinawan vegetables in young healthy participants should be a dietary recommendation in public health programs for Okinawans. The hypothesized increase in potassium via intake of these vegetables could be an inexpensive natural way to lower high blood pressure and promote cardiovascular health.

**Inclusion Criteria:**

- Free-living female volunteers living in Okinawa
- Between 18 and 38 years of age
- Healthy and not undergoing any treatment for any disease at the time of the study
- Informed, written consent was obtained

**Exclusion Criteria:**

- Male
- Under 18 years of age or older than 38 years of age
- Residing outside of Okinawa
- Undergoing active treatment for any disease at the time of the study

**Description of Study Protocol:**

**Recruitment**

- Recruited participants through posters and personal contacts

**Design**

- Randomized controlled trial: Subjects were randomized into two groups (method not

described): dietary intervention group and control group

## **Intervention**

- Dietary intervention participants were provided:
  - A list of yellow-green Okinawan vegetables being used in the study
  - Instructions on how to cook the Okinawan vegetables
  - Strong urging to consume the Okinawan vegetables as part of their diet
  - 2.6 kg total of a combination of five typical yellow green Okinawan vegetables delivered (twice a week, 1.3 kg per delivery) to participants homes via express home parcel delivery service, containing approximately:
    - 400 g Goya
    - 600 g green papaya
    - 100 g Handama
    - 100 g Karashina
    - 100 g of three other vegetables (Njana, Fuchiba, or Fudanso)

## **Statistical Analysis**

- Paired sample t-test to measure changes within each group
- Student's independent sample t-test to assess differences between groups
- Wilcoxon matched pair and Mann-Whitney U tests for variables that could not be normalized after logarithmic transformation
- Pearson correlation to look at relationships between vegetable intake and post-intervention urinary sodium and potassium excretion

## **Data Collection Summary:**

### **Timing of Measurements**

Data collection one day pre and post intervention:

- Blood pressure
  - Systolic and diastolic
- Anthropological data
  - Age, height, weight, body mass index (BMI)
- Blood sample (fasting)
  - High density lipoprotein (HDL), low density lipoprotein (LDL), total cholesterol, triglycerides, folic acid
- Urine sample (24 hour)
  - Sodium, potassium, magnesium, sodium-potassium ratio

Dietary assessment (with digital scale and picture booklet)

- Self-reported intake of all vegetables, fruits and juices consumed

### **Dependent Variables**

- Urinary potassium excretion was a primary endpoint, but also examined:
  - Urine sodium, magnesium, sodium-potassium ratio
  - Serum cholesterol, HDL, LDL, triglycerides, folic acid
  - Blood pressure

### **Independent Variables**

- Increased dietary intake of yellow-green Okinawan vegetables

## Control Variables

### Description of Actual Data Sample:

**Initial N:** N = 53 (25 in dietary intervention group, 29 in control group)

#### Attrition (final N):

N=39 (19 in dietary intervention group, 20 in control group)

Attrition due to incomplete data. Exclusion due to creatinine/body weight ratio less than 10.8 or greater than 25.2, and cigarette smoking.

#### Age:

Intervention group: 24.4±3.8 years

Control group: 25.7±4.8 years

**Ethnicity:** Japanese/Okinawan.

#### Other relevant demographics:

#### Anthropometrics

Body mass index (BMI) (NS):

- Intervention: 20.1±1.4
- Control: 21.1±3.1

Height (cm) (NS):

- Intervention: 156.4±4.4
- Control: 158.1±5.2

Weight (kg) (NS):

- Intervention: 49.3±4.8
- Control: 52.7±6.9

#### Location:

Okinawa, Japan

### Summary of Results:

#### Key Findings

- There were no statistical differences between the intervention and control groups pre-intervention.
- Increases in intake of typical yellow-green Okinawan vegetables significantly (P=0.047) increased urinary potassium excretion (363.5±0.045 mg/day) in the intervention group.
- The correlation between Okinawan vegetable consumption and urinary potassium excretion

in the dietary intervention group was stronger than the correlation between the intake of other vegetables and urinary potassium excretion in the control group ( $r=0.73$ ,  $p=0.0004$  and  $r=0.56$ ,  $p=0.010$ )

- There were also significant correlations between average daily all vegetable intake and urinary potassium excretion in both the intervention and control groups ( $p<0.0001$  and  $p=0.008$ )

#### Pre- and Post-Intervention Changes in Dietary Intervention Group

	Pre-Intervention Dietary Intervention Group	Post-Intervention Dietary Intervention Group	Statistical Significance
Urinary potassium (24 hour; mg/day)	1600.9±474.0	363.5	$p=0.045$
Urinary sodium-potassium ratio (24 hour; mg/day)	1.9±0.8	-0.4	$p=0.039$

#### Between Group Post-Intervention Change Comparison

	Post-Intervention Dietary Intervention Group Changes	Post-Intervention Control Group Changes	Statistical Significance
Urinary potassium (24 hour; mg/day)	363.5	-68.6	$p=0.047$
Urinary sodium-potassium ration (24 hour; mg/day)	-0.4	0.1	$p=0.031$

#### Average Dietary Intake of Vegetable, Fruit and Overall Potassium Intake (g/day)

	Dietary Intervention Group	Control Group	Statistical Significance
Vegetables	251.3±78.4	153.7±74.5	$p=<0.001$
Average daily Okinawan vegetable intake	144.9±66.9	4.7±5.8	$p=<0.001$

### Other Findings

- There were no statistical differences between the intervention and control groups pre-intervention.
- Post-intervention changes and differences, other than noted above, were not significant. This includes: mean urinary sodium and magnesium excretions, serum HDL cholesterol, LDL cholesterol, and total cholesterol, folic acid and triglycerides.
- Of the 371g/day provided of Okinawan vegetables for the intervention group, of which only about half of that was reportedly consumed daily.
- The control group consumed a higher amount of fruit, but it was not statistically significant from the intervention group nor was the potassium intake from fruits.
- On average, Okinawan vegetables provided about 40% more potassium than other vegetables.
- There were no significant correlations between changes in blood pressure and potassium excretions in either group.

### Author Conclusion:

Increasing the consumption of yellow-green Okinawan vegetables increased urinary potassium excretion, which is a reflection of higher intake and higher bioavailability. Preventive public health programs promoting higher intakes of dietary potassium in Okinawans could consider increases in yellow-green Okinawan vegetables as a low cost, non-pharmological method to promote normotensive blood pressure and cardiovascular health.

### Reviewer Comments:

- *Unable to tell if age was an inclusion/exclusion criteria or if it was simply noted as a description of the sample. This reviewer chose to list it as an inclusion/exclusion criteria*
- *Question the use of "personal contacts" as a subject recruitment tool to maintain unbiased subjects, although outcome measures were largely objective (lab results.)*
- *Assume ethnicity to be Asian; noted that participants resided in Okinawa*
- *Small sample size as well as the short intervention period may cause some differences to be undetected*
- *Limitations in self-reported data; participants may have underreported intake of vegetables (vegetable intake was approximately 50% of what was delivered)*
- *Study did not include hypertensives so true effect on blood pressure may not be detected*
- *Method of randomization not described*
- *No mention of blinding of subjects or investigators*

## Research Design and Implementation Criteria Checklist: Primary Research

### Relevance Questions

- |    |   |     |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?   | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?  | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies)  | Yes |

### Validity Questions

- |      |   |     |
|------|---|-----|
| 1.   | <b>Was the research question clearly stated?</b>  | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?   | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated?  | Yes |
| 1.3. | Were the target population and setting specified?   | Yes |
| 2.   | <b>Was the selection of study subjects/patients free from bias?</b>   | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups?  | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described?   | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population?  | Yes |
| 3.   | <b>Were study groups comparable?</b>  | No  |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)   | No  |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?  | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.)   | Yes |

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	<b>Yes</b>
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes

8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	<b>Yes</b>
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	<b>Yes</b>
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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